

2-39-00240-134

Number (%) of Patients reporting Non Serious AE by Primary System Organ Class and Preferred term (Double-Blind and Follow-Up period)
Safety Population

All (N=49)			
Primary system organ class preferred term	Double-blind		Follow-Up ¹²
	Egb761 in DB period (N=23)	Placebo in DB period (N=26)	Egb761 (N=41)
PRIMARY SOC PT			
ANY TEAEs	5 (21.7)	9 (34.6)	23 (56.1)
GASTROINTESTINAL DISORDERS	1 (4.3)	1 (3.8)	10 (24.4)
Constipation	0	0	3 (7.3)
Diarrhoea	1 (4.3)	0	2 (4.9)
Gastrooesophageal reflux disease	0	0	2 (4.9)
Aerophagia	0	0	1 (2.4)
Nausea	0	0	1 (2.4)
Food poisoning	0	0	1 (2.4)
Gastrointestinal disorder	0	1 (3.8)	0
Vomiting	1 (4.3)	0	0

All (N=49)			
Primary system organ class preferred term	Double-blind		Follow-Up ¹²
	Egb761 in DB period (N=23)	Placebo in DB period (N=26)	Egb761 (N=41)
PRIMARY SOC PT			
NERVOUS SYSTEM DISORDERS	1 (4.3)	4 (15.4)	9 (22.0)
Dementia Alzheimer's type	0	1 (3.8)	2 (4.9)
Headache	1 (4.3)	0	1 (2.4)
Tremor	0	1 (3.8)	1 (2.4)
Carpal tunnel syndrome	0	0	1 (2.4)
Dizziness	0	0	1 (2.4)

All (N=49)			
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	Egb761 in DB	Placebo in DB	
	period (N=23)	period (N=26)	
PRIMARY SOC PT			Egb761 (N=41)
Essential tremor	0	0	1 (2.4)
Hemicephalalgia	0	0	1 (2.4)
Neuralgia	0	1 (3.8)	1 (2.4)
Syncope vasovagal	0	1 (3.8)	0

All (N=49)			
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	Egb761 in DB	Placebo in DB	
	period (N=23)	period (N=26)	
PRIMARY SOC PT			Egb761 (N=41)
INFECTIONS AND INFESTATIONS	0	0	6 (14.6)
Bronchitis	0	0	2 (4.9)
Pharyngitis	0	0	1 (2.4)
Urinary tract infection	0	0	1 (2.4)
Bronchopneumonia	0	0	1 (2.4)
Ear infection	0	0	1 (2.4)
Gastroenteritis viral	0	0	1 (2.4)
Herpes zoster	0	0	1 (2.4)
Tracheobronchitis	0	0	1 (2.4)
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	0	1 (3.8)	4 (9.8)

		All (N=49)		
PRIMARY SOC PT	Primary system organ class preferred term	Double-blind		Follow-Up ¹²
		EGb761 in DB period (N=23)	Placebo in DB period (N=26)	EGb761 (N=41)
	Dry skin	0	0	1 (2.4)
	Pigmentation disorder	0	0	1 (2.4)
	Rash	0	1 (3.8)	1 (2.4)
	Dermal cyst	0	0	1 (2.4)
	PSYCHIATRIC DISORDERS	1 (4.3)	0	6 (14.6)
	Depression	0	0	3 (7.3)
	Insomnia	0	0	3 (7.3)
	Anxiety	0	0	1 (2.4)
	Delirium	1 (4.3)	0	0
	INJURY, POISONING AND PROCEDURAL COMPLICATIONS	1 (4.3)	1 (3.8)	5 (12.2)

Primary system organ class preferred term	All (N=49)		
	Double-blind		Follow-Up ¹² EGb761 (N=41)
	EGb761 in DB	Placebo in DB	
	period (N=23)	period (N=26)	
PRIMARY SOC PT			
Fall	1 (4.3)	0	5 (12.2)
Spinal fracture	0	0	1 (2.4)
Wound	0	0	1 (2.4)
Procedural nausea	0	1 (3.8)	0
CARDIAC DISORDERS	0	0	2 (4.9)
Palpitations	0	0	1 (2.4)
Tachycardia	0	0	1 (2.4)
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	0	2 (7.7)	2 (4.9)
Dyspnoea	0	2 (7.7)	2 (4.9)

		All (N=49)		
PRIMARY SOC PT	Primary system organ class preferred term	Double-blind		Follow-Up ¹² Egb761 (N=41)
		Egb761 in DB	Placebo in DB	
		period (N=23)	period (N=26)	
	Rhinitis allergic	0	0	1 (2.4)

Primary system organ class preferred term	All (N=49)		
	Double-blind		Follow-Up ¹²
	EGb761 in DB	Placebo in DB	
	period (N=23)	period (N=26)	
PRIMARY SOC PT			EGb761 (N=41)
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	0	2 (7.7)	5 (12.2)
Back pain	0	2 (7.7)	1 (2.4)
Arthralgia	0	0	2 (4.9)
Musculoskeletal pain	0	0	1 (2.4)
Neck pain	0	0	1 (2.4)
Tendonitis	0	0	1 (2.4)
Myalgia	0	1 (3.8)	0
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	1 (4.3)	0	3 (7.3)
Asthenia	0	0	1 (2.4)
Fatigue	1 (4.3)	0	1 (2.4)

		All (N=49)		
PRIMARY SOC PT	Primary system organ class preferred term	Double-blind		Follow-Up ¹² EGb761 (N=41)
		EGb761 in DB	Placebo in DB	
		period (N=23)	period (N=26)	
	Oedema peripheral	0	0	1 (2.4)

All (N=49)			
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	Egb761 in DB	Placebo in DB	
	period (N=23)	period (N=26)	
PRIMARY SOC PT			Egb761 (N=41)
EAR AND LABYRINTH DISORDERS	0	1 (3.8)	2 (4.9)
Vertigo	0	1 (3.8)	2 (4.9)
EYE DISORDERS	0	0	2 (4.9)
Macular degeneration	0	0	1 (2.4)
Vision blurred	0	0	1 (2.4)
Cataract	0	0	1 (2.4)
RENAL AND URINARY DISORDERS	0	0	2 (4.9)
Urinary incontinence	0	0	1 (2.4)
Renal colic	0	0	1 (2.4)

All (N=49)			
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	Egb761 in DB	Placebo in DB	
	period (N=23)	period (N=26)	
PRIMARY SOC PT			Egb761 (N=41)
VASCULAR DISORDERS	1 (4.3)	0	2 (4.9)
Orthostatic hypotension	1 (4.3)	0	1 (2.4)
Haematoma	0	0	1 (2.4)
Hypertension	0	0	1 (2.4)
METABOLISM AND NUTRITION DISORDERS	0	0	1 (2.4)
Hypercholesterolaemia	0	0	1 (2.4)
REPRODUCTIVE SYSTEM AND BREAST DISORDERS	0	0	1 (2.4)
Benign prostatic hyperplasia	0	0	1 (2.4)

Dictionary Name: MedDRA Version 11.1

Note: Format is number of patients (percent of patients). If a patient experienced more than one event in a category, the patient was counted only once in that category
Primary SOC sorted by decreasing frequency in MC group then in CNE group and PT sorted by decreasing frequency in MC group then in CNE group
Percentages are based on the number of patients in the Safety population.
¹: 2 CNE patients withdrew during the Double-Blind period and were also not included in the Safety Population for the FU period
²: 1 MC patient withdrew during the Double-Blind period and was also not included in the Safety Population for the FU period